Amendments to the Specification:

Please replace the paragraph bridging pages 15 and 16 of the clean copy of the Substitute Specification, submitted with the Preliminary Amendment when the present application was filed on June 26, 2006, with the following replacement paragraph:

Aqueous solutions were prepared containing 200, 300 and 400 mg/ml of three types of cyclodextrin. These were ~~hydroxypropyl-□-cyclodextrin~~ hydroxypropyl-β-cyclodextrin (HP-CD) (Cavamax® W7 HP Pharma, Wacker, Germany), ~~methylated-□-cyclodextrin~~ methylated-β-cyclodextrin (M-CD) (Cavamax® W7 M Pharma, Wacker) and ~~sulfobutylether-□-cyclodextrin~~ sulfobutylether-β-cyclodextrin (SBE-CD) (Captisol®, CyDex, USA). 25 mg samples of zolpidem tartrate (ZMC, Zheijang, Hangzhou, China) were added to a 0.5 ml portion of each cyclodextrin solution. The mixtures (containing 50 mg/ml drug) were stirred overnight at room temperature. If drug dissolved then more was added. If undissolved drug remained then an additional 0.5 ml of cyclodextrin solution was added and stirring continued. From this experiment an estimate could be made of zolpidem tartrate solubility in the different cyclodextrin solutions. Results are summarised in Table 1.

Please replace the paragraph bridging pages 17 and 18 of the clean copy of the Substitute Specification, submitted with the Preliminary Amendment when the present application was filed on June 26, 2006, with the following replacement paragraph:

5 g of SBE-CD was weighed into a 25 ml volumetric flask and dissolved by adding approximately 15 ml of water followed by stirring. 1.25 g of zolpidem tartrate was added to the volumetric flask together with an additional 5 ml of water and 0.25 ml of 15 mg/ml benzalkonium chloride stock solution. The solution was adjusted to approximately pH 4.5 by the addition of 0.1M hydrochloric acid solution (prepared by dilution of concentrated hydrochloric acid (Fisher)) and then made up to 25 ml with water. The solution was passed through a

0.45 ~~□m~~ μm membrane filter (Sartorius, Leicester, UK) and the pH measured. The final solution was at pH 4.6.

Please replace the paragraph at page 18, lines 8-16, of the clean copy of the Substitute Specification, submitted with the Preliminary Amendment when the present application was filed on June 26, 2006, with the following replacement paragraph:

10 g of SBE-CD and 250 mg of chitosan glutamate (Protasan UPG213, NovaMatrix, Drammen, Norway) were weighed and transferred into a 50 ml volumetric flask and dissolved by adding approximately 30 ml of water followed by stirring. 2.5 g of zolpidem tartrate was added to the volumetric flask together with an additional 10 ml of water and 0.5 ml of 15 mg/ml benzalkonium chloride stock solution. The solution was adjusted to approximately pH 4.5 by the addition of 0.1M hydrochloric acid solution and then made up to 50 ml with water. The solution was passed through a 0.45 ~~□m~~ μm membrane filter (Sartorius, Leicester, UK) and the pH measured. The final solution was at pH 4.7.

Please replace the paragraph at page 18, lines 24-29, of the clean copy of the Substitute Specification, submitted with the Preliminary Amendment when the present application was filed on June 26, 2006, with the following replacement paragraph:

50 mg of zolpidem tartrate was weighed into a 50 ml volumetric flask and dissolved by adding 40 mg of water. 445 mg of sodium chloride (Sigma, Poole, UK) was added to the volumetric flask and dissolved by stirring. The solution was made up to 50 ml by adding water. In a laminar flow cabinet the solution was sterile filtered (0.2 ~~□m~~ μm membrane filter) into sterile injection vials that were sealed with elastomeric closures and aluminium caps.